

# **EXHIBIT A**

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

---

In re: MEDTRONIC, INC.  
IMPLANTABLE DEFIBRILLATORS  
PRODUCT LIABILITY LITIGATION

Multidistrict Litigation No.  
05-1726 (JMR/AJB)

THIS DOCUMENT RELATES TO ALL  
CASES

---

**MEMORANDUM IN SUPPORT OF MEDTRONIC, INC.'S MOTION TO  
STRIKE, FOR PARTIAL DISMISSAL AND FOR SEVERANCE OF CERTAIN  
CLAIMS**

**INTRODUCTION**

With only vague references to two Medtronic products in three Complaints as their means, Plaintiffs now seek to distort this MDL far beyond the scope of the actions that gave rise to this proceeding. No plaintiff in any Complaint transferred to this MDL ever was implanted with, or claims to have suffered an injury from, Medtronic's defibrillators Micro Jewel II Model 7223 Cx ("Micro Jewel II") or Gem DR Model 7271 ("Gem DR") and neither of these models experienced the potential for premature battery depletion that gave rise to the February 2005 action. Plaintiffs have nonetheless improperly pressed to include these unrelated devices in the MDL.

This MDL—involving eight distinct models of the Marquis family, with batteries manufactured by Medtronic between April 2001 and December 2003—should not become a platform for wholesale discovery of Medtronic's entire defibrillator inventory.

Plaintiffs should not be permitted to sweep into this proceeding any defibrillator bearing the Medtronic brand without regard to whether it was addressed by the February 2005 voluntary field action. Nor should Plaintiffs, based upon the mere suggestion that other Medtronic defibrillators have been subject to a different field action, be entitled to expanded discovery to devices from which no Plaintiff claims injury and thus has no standing to assert a product liability claim.

The fairness and efficiency of this MDL proceeding will evaporate if Plaintiffs are allowed to expand these proceedings beyond the common questions of fact that were the predicate for consolidation in the first place. Allegations regarding any Medtronic devices *outside* the scope of the February 2005 voluntary field action do not belong in this MDL and should be stricken, dismissed or severed.

## **BACKGROUND**

### **A. The February 2005 Marquis Field Action**

In February 2005, Medtronic voluntarily undertook to notify physicians and patients that a remote possibility existed that certain of its implantable cardioverter defibrillators (“ICDs”) and cardiac resynchronization therapy defibrillators (“CRT-Ds”), with batteries manufactured between April 2001 and December 2003, could experience premature battery depletion. Specifically, Medtronic advised that certain Marquis devices could experience rapid battery depletion due to a specific internal battery short mechanism. A true and correct copy of the February 2005 field action (“Marquis field action”) notification is attached to the Affidavit of Tracy J. Van Steenburgh as Exhibit A.

The Marquis field action involved eight specific models of Medtronic ICDs and CRT-Ds (the “Marquis field action devices”):

- Marquis VR Model 7230;
- Marquis DR Model 7274;
- Maximo VR Model 7232;
- Maximo DR Model 7278;
- In Sync Marquis Model 7277;
- In Sync II Marquis Model 7289;
- In Sync III Marquis Model 7279;
- In Sync III Protect Model 7285<sup>1</sup>.

Within six weeks after the Marquis field action, Medtronic was served with the first Marquis field action device Complaint. In that Complaint and in every subsequent Complaint, the named plaintiff has alleged either that the battery in their Marquis device was at risk of premature depletion or they had elected to have their Marquis device explanted as a result of the Marquis field action. Although every Complaint contains claims about the Marquis field action devices, in three Complaints, the plaintiffs embellished their allegations about the Marquis field action devices with extraneous statements about two unrelated Medtronic devices, the Micro Jewel II and Gem DR. *See Ware, et al v. Medtronic, Inc., et al.*, 0:05-61468 (S.D. Fla.), *Vantosh, et al. v. Medtronic, Inc.*, 9:05-80782 (S.D. Fla.), and *Pearson v. Medtronic, Inc.*, 2:05-00779 (C.D. Utah),

---

<sup>1</sup> Although covered by the February 2005 field action, the In Sync III Protect, Model 7285 was never sold in the United States and thus, should not be part of this MDL either as discussed with the Court previously.

attached to Affidavit of Tracy J. Van Steenburgh as Exhibits B, C and D. In the *Vantosh* and *Pearson* Complaints, the plaintiffs, without more, merely identified the Micro Jewel II and Gem DR devices on a list of devices made by Medtronic. *Vantosh Complaint* at ¶7; *Pearson Complaint* at ¶ 7. In the *Ware* Complaint, the plaintiff added a general allegation that the Micro Jewel II and Gem DR devices had been subject to a field action in April 2004. *Ware Complaint* at ¶ 9. In notable contrast to allegations by named plaintiffs implanted with a Marquis device, the plaintiffs in these three Complaints make no claim that any of them was ever implanted with or injured by a Gem DR or Micro Jewel II device. Moreover, Plaintiffs have recently created a Master Consolidated Complaint for Individuals, in which they include enhanced statements about the Micro Jewel II and Gem DR devices; however, as discussed *infra*, Plaintiffs carefully omit any reference to any plaintiff having received or been injured by the Micro Jewel II and Gem DR devices.

**B. The JPML Created MDL 1726 to Coordinate Pretrial Proceedings of Marquis Field Action Device Cases with Common Issues**

On August 26, 2005, Plaintiffs brought a motion before the Judicial Panel on Multidistrict Litigation (“JPML”), seeking transfer, coordination, and consolidation of putative class actions and individual product liability actions against Medtronic then pending in various federal courts.<sup>2</sup> All of those movants were recipients of a Marquis field action device and all of the referenced Complaints asserted claims based upon the February 2005 field action. By contrast, the only mention of the Micro Jewel II or Gem

---

<sup>2</sup> The individual Plaintiffs have withdrawn all class action allegations; however, the third-party payors continue to pursue class claims.

DR devices were the passing references in the three Complaints noted above. Nothing had changed by the time of the hearing before the JPML on November 17, 2005 -- not a single named plaintiff in any case had asserted implantation with or injury related to a Micro Jewel II or Gem DR device.

On December 7, 2005, the JPML created MDL 1726 and transferred 25 pending actions and 14 potential tag-along actions involving Marquis ICDs and CRT-Ds to this Court for coordinated pretrial proceedings. Still, not one plaintiff in any of the transferred actions alleged implantation of a Micro Jewel II or Gem DR device. Instead, the focus of the MDL was the Marquis field action devices. The JPML transferred the actions to this Court, finding they involved common questions of fact, witnesses and evidence. A true and correct copy of the JPML December 7, 2005 Transfer Order ("Transfer Order") is attached to the Van Steenburgh Aff. as Exhibit E.

**C. The February 2005 and April 2004 Field Actions Involved Completely Different Devices and Potential Failure Mechanisms**

Despite the absence of a plaintiff who in fact received a Micro Jewel II or Gem DR device, from the inception of the MDL, Plaintiffs' counsel, without basis, have persistently sought to include those devices by inserting references to them in various pleadings and proposals. They insinuate a linkage between the Micro Jewel II and Gem DR devices and the Marquis field action devices based on an April 2004 field action involving only the Micro Jewel II and Gem DR devices. In the April 2004 field action, Medtronic voluntarily notified physicians and patients that in approximately 1386 active

Micro Jewel II devices and approximately 435 active Gem DR devices (all identifiable by serial number) the capacitors might not be capable of consistently and timely providing the energy necessary to the performance of the devices near the end of the devices' normal life. A true and correct copy of the April 2004 field action notification is attached to Van Steenburgh Aff. as Exhibit F. Far from establishing a link with the Marquis field action devices, however, the April 2004 field action demonstrates important differences between those devices and issues relative to the Marquis field action in 2005.

The Micro Jewel II and Gem DR devices are significantly different from the Marquis field action devices in terms of the battery, potential failure mechanism, potential result, and field actions to name a few. The most significant difference lies with the "power source." Neither the Micro Jewel II nor the Gem DR has as its power source the specific battery, which was manufactured by Medtronic between April 2001 and December 2003, and which is the focus of this MDL. The key differences include:

	<b>Marquis Field Action Devices</b>	<b>Micro Jewel II/Gem DR Devices</b>
<b>Battery</b>	<ul style="list-style-type: none"> <li>Each battery consists of a single cell</li> <li>Cells are lithium limited</li> <li>Manufactured by Medtronic Energy and Components Center</li> </ul>	<ul style="list-style-type: none"> <li>Each battery consists of two cells</li> <li>Cells are cathode limited</li> <li>Manufactured by Wilson Greatbatch (independent contractor)</li> </ul>
<b>Potential Failure Mode</b>	<ul style="list-style-type: none"> <li>Battery</li> </ul>	<ul style="list-style-type: none"> <li>Capacitor</li> </ul>
<b>Potential Result</b>	<ul style="list-style-type: none"> <li>Potential rapid battery depletion due to specific internal battery short mechanism, meaning battery shorting may deplete battery life faster</li> </ul>	<ul style="list-style-type: none"> <li>Potential that capacitors might not be consistently capable of providing high voltage energy delivery, meaning potential impact on charge time</li> </ul>
<b>Field Action/Patient Management Options<sup>3</sup></b>	<ul style="list-style-type: none"> <li>February 2005</li> <li>Limited to Marquis family of devices with batteries manufactured between April 2001 and December 2003 with specific serial numbers</li> </ul>	<ul style="list-style-type: none"> <li>April 2004</li> <li>Limited to subset of Micro Jewel II Model 7223CX and Gem DR Model 7271 devices implanted in 1997 and 1998</li> </ul>

The battery, potential failure mechanism, potential result, and field action differences necessarily mean that important and significant differences would create hurdles for this MDL were those unrelated devices to be included. The evidence and documents for the Marquis field action devices are distinct and different from the Micro Jewel II and Gem DR devices. Also, an entirely different universe of witnesses who may have knowledge about the Micro Jewel II and Gem DR devices is involved.

<sup>3</sup> See Exhibits A (February 2005 field action notification) and F (April 2004 field action notification) to Van Steenburgh Aff. for the different patient management options.



**D. The Marquis Field Action Did Not Include Other Unrelated Devices**

Since the creation of the MDL, Plaintiffs have further sought to include Marquis devices *not* subject to the Marquis field action. Marquis devices subject to the February 2005 field action have batteries produced between April 2001 and December 2003 and are identified by a specific serial number. Any device without an affected serial number (*i.e.* manufactured with batteries made after December 2003) should not be included in this MDL because there are no facts or evidence in common. Yet, for example, in the *Willis v. Medtronic, Inc.* Complaint, 3:05-2020 (D.S.C.), attached to Van Steenburgh Aff. as Exhibit G, Plaintiff asserts a claim involving a Marquis device that was not part of the Marquis field action; its battery was not manufactured during the April 2001 through December 2003 time frame. In the *Lynn v. Medtronic, Inc.* Complaint, 06-CV-430, (D. Minn.), attached to Van Steenburgh Aff. as Exhibit H, although referred to as a Marquis device, the device at issue is actually a CRT, a non-Marquis device. Any claims asserted in connection with non-field action Marquis ICDs and CRT-Ds or non-Marquis devices are also unrelated to this MDL and do not belong here.

**ARGUMENT**

Plaintiffs fought for an MDL because they claimed that common facts and issues existed relating to their alleged injuries from Marquis devices subject to the Marquis field action. There have never been any cases brought here in which a plaintiff claimed to have either been implanted with, or injured by, a Micro Jewel II or Gem DR device.

Plaintiffs' references to the Micro Jewel II and Gem DR devices were presumably made solely to imply Medtronic was negligent in the design of the Marquis battery simply because it had undertaken an earlier field action on other devices. Plaintiffs' statements about the Micro Jewel II and Gem DR devices are irrelevant and do not provide a basis to include these two devices in the MDL.

Plaintiffs have also tried to expand the scope of the MDL by filing Complaints dealing with non-field action Marquis devices. Any such Complaint is distinct from Marquis field action devices. Just as the Vioxx MDL should not be a dumping ground for complaints by Merck patients who have taken Zocor, this MDL should not be used as a free-for-all for any and all comers with a possible product liability claim against Medtronic.

**A. Plaintiffs' Attempt to Include Micro Jewel II and Gem DR Device Claims is Procedurally, Factually and Legally Without Basis.**

By including references in three Complaints and in the Master Complaint to the Micro Jewel II and Gem DR devices and by asserting claims involving Marquis devices *not* subject to the Marquis field action, Plaintiffs seek to improperly expand the scope of the MDL. Their overreaching lacks factual, procedural and substantive justification.

**1. Statements and Allegations Involving the Micro Jewel II and Gem DR Devices Should Be Stricken**

Rule 12(f) of the Federal Rules of Civil Procedure provides:

Upon motion made by a party before responding to a pleading or, if no responsive pleading is permitted by these rules, upon motion made by a party within 20 days after the service of the pleading upon him or upon the

court's own initiative at any time, the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.

"Immaterial" matter is "that which has no essential or important relationship to the claim for relief or the defenses being pleaded. . . . "Impertinent" matter consists of statements that do not pertain and are not necessary, to the issues in question. *In re Potash Antitrust Litig.*, 1994 WL 1108312 (D. Minn. Dec. 5, 1994) (Erickson, MJ) (striking paragraphs not directed to events that lay in close proximity to acts forming basis of claims). *See also Vandanacker v. Main Motor Sales Co.*, 109 F. Supp. 2d 1045, 1047 (D. Minn. 2000) (Doty J.) (motion to strike under Rule 12(f) is appropriate remedy for elimination of "redundant, immaterial, impertinent, or scandalous matter" in a pleading).

Statements (and hypothetical allegations) regarding the Micro Jewel II and Gem DR devices should be stricken from the Master Complaint and any other Complaint. Strategic placement of references to the Micro Jewel II and Gem DR devices in the Master Complaint are obviously included to suggest that Medtronic, because of an earlier field action, must be negligent with respect to the Marquis field action devices. Plaintiffs have attempted to augment the vague references to the devices in the *Vantosh*, *Ware* and *Pearson* Complaints by adding more "facts." Not only are such references to the Micro Jewel II and Gem DR devices immaterial and impertinent, they do not represent legitimate claims by injured persons. The references to the Micro Jewel II and Gem DR devices have no relationship whatsoever to the allegations relating to the Marquis devices subject to the Marquis field action. Not only were the Gem DR and Micro Jewel II devices *not* included in the February 2005 field action, there is absolutely nothing about

the Micro Jewel II or Gem DR devices that overlaps, explains, or is necessary to any claim involving the Marquis field action devices. The evidence and witnesses relative to any claim (hypothetical at this stage) involving a Micro Jewel II or Gem DR device are different from the evidence and witnesses relative to the Marquis field action devices. Plaintiffs cannot be permitted to elevate extraneous and irrelevant statements about two devices that happen to be manufactured by Medtronic into a basis for conducting broad discovery about devices that are not part of this MDL. Certainly, had Plaintiffs stated in a Complaint that Medtronic is a world leader in medical device manufacturing and listed Medtronic's spinal implants, they would not be permitted to expand this MDL to include spinal hooks, rods and screws. Similarly, they should not be allowed, based on the mere statements about the Micro Jewel II and Gem DR devices, to unilaterally and unfairly broaden the scope of this MDL

**2. Plaintiffs Lack Standing to Pursue Claims Involving the Micro Jewel II and Gem DR Devices**

Plaintiffs' attempt to create a "floating" MDL under which they can assert claims regarding unrelated devices is not only procedurally deficient but also substantively deficient. Under Article III of the Constitution, federal courts have jurisdiction only over "Cases" and "Controversies." U.S. Const. art. III, § 2, cl. 1. Standing "is an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130 (1992). If a plaintiff lacks Article III standing, a court has no subject matter jurisdiction to hear a claim. *American*

*Assoc. of Orthodontists v. Yellowbook USA, Inc.*, - F.3d -, 2006 WL 162979 (8th Cir. 2006).

Three elements comprise the “irreducible constitutional minimum of standing.” *Defenders of Wildlife*, 504 U.S. at 560, 112 S. Ct. at 2130. First, a plaintiff must have suffered an “injury in fact” – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. *Id.* Second, “there must be a causal connection between the injury and the conduct complained of – the injury has to be fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.” *Id.* at 560-61, 112 S. Ct. 2130 (internal quotation marks omitted). Third, “it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Id.* at 561, 112 S. Ct. 2130 (internal quotation marks omitted).

The “party invoking federal jurisdiction bears the burden of establishing these elements.” *Id.* To successfully invoke federal jurisdiction here, plaintiffs bear the burden of establishing they have suffered a concrete injury, or are on the verge of suffering one. *Id.* In references to the Micro Jewel II and Gem DR devices in the *Ware*, *Vantosh*, and *Pearson* Complaints, Plaintiffs do not allege an injury has occurred or is about to occur due to the Micro Jewel II or Gem DR.<sup>4</sup> Instead, they merely observe that Medtronic

---

<sup>4</sup> Specifically, Plaintiffs Ware and Young allege that they received a Medtronic Marquis VR and Medtronic Marquis DR respectively. See Exhibit B to Van Steenburgh Aff. at ¶¶ 19 and 21. Plaintiff Vantosh alleges that he received a Medtronic In Sync II Marquis. Exhibit C to Van Steenburgh Aff. at ¶¶ 12 and 14. Plaintiff Pearson alleges he received a Medtronic Marquis DR Model 7274. Exhibit D to Van Steenburgh Aff. at ¶ 12.

undertook a field action in April 2004 involving these two devices. Similarly, in the Master Complaint, Plaintiffs carefully avoid stating that any plaintiff has received or been injured by a Micro Jewel II or Gem DR device but, instead, again observe that Medtronic undertook a field action and issued a press release about the field action. Master Consolidated Complaint for Individuals at ¶¶ 49-57. Such allegations do not come close to establishing an injury-in-fact sufficient to fulfill that threshold requirement of standing. *Defenders of Wildlife*, 504 U.S. at 560-61. Consequently, this Court lacks subject matter jurisdiction over any hypothetical claim referencing the Micro Jewel II or Gem DR devices.

The same is true of the In Sync III Protect, Model 7285 device. Although included as part of the Marquis field action, the In Sync III Protect device was never sold for use in the United States. There is no named plaintiff who received the 7285 device. Consequently, there is no legal basis for including claims relating to that device in this proceeding. *Warth*, 422 U.S. at 498.

The creation of an MDL does not suspend the ordinary principles of jurisprudence. Hypothetical claims based on what might or might not have happened to someone else have no place here. These proceedings were initiated by people who claimed to be injured by the implantation of Marquis devices in the United States that were subject to the February 2005 field action. Those actual claims must alone define the scope of these proceedings.

**B. All Claims Involving Marquis Non-Field Action Devices or Non-Marquis Devices Should Be Severed and Remand Suggested.**

Complaints recently served on Medtronic involve devices with batteries that were *not* manufactured between April 2001 and December 2003—in other words, non-field action Marquis devices. This Court should sever and suggest remand for any claims or allegations regarding: (1) Marquis devices with batteries not made between April 2001 and December 2003 and (2) non-Marquis devices. Although Plaintiffs who have received non-field action Marquis devices (or *any* device *not* part of the February 2005 field action) may have standing to assert claims, those claims do not belong in this MDL. The key issues in the MDL will surround the specific batteries and battery design in the Marquis devices subject to the February 2005 field action. Non-field action Marquis devices contain a different battery from the battery manufactured between April 2001 and December 2003. For example, the *Willis* Complaint alleges that Plaintiff had a Marquis DR Model 7274 implanted on or about February 18, 2004. Exhibit G to Van Steenburgh Aff. at ¶ 12. Plaintiff's device does not contain a battery manufactured between April 2001 and December 2003, however, and thus does not come within the Marquis field action. Similarly, in *Lynn*, Plaintiff does not even have a Marquis device. Hence, claims alleging injury from non-Marquis field action devices, such as *Willis* or *Lynn*, do not involve the same transaction, common questions of fact, or the same evidence as claims

arising from implanted field-action Marquis devices. Consequently, such actions should also be severed from this MDL.<sup>5</sup>

**1. Severance Promotes Efficiency in the Administration of This MDL**

If parties or claims are joined improperly, the remedy is found in Federal Rule of Civil Procedure 21, which states:

Misjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just. Any claim against a party may be severed and proceeded with separately.

*See also, Madison v. Hennepin County*, 203 WL 21639176 (D. Minn. July 1, 2003). To determine whether parties or claims are properly joined, the requirements of Rule 20, in turn, must be met. Rule 20 requires that a plaintiff show both that (1) their claim arises out of the same transaction or occurrence and (2) a question of law or fact common to all joined parties will arise. *Mosely v. General Motors Corp.*, 497 F.2d 1330, 1332 (8th Cir. 1974). *See also In re Baycol Products Liab. Litig.*, 2002 WL 32155269 (D. Minn. July 5, 2002) (Davis, J.) (discussing joinder in context of joinder of parties and stating joinder proper where plaintiffs' claims arise from same basic set of facts).

Severance is an especially important tool available to the Court in an MDL proceeding because it promotes the just and efficient conduct of the litigation by eliminating disparate claims arising from facts other than those that led to the creation of the MDL. *See e.g., Zyprexa Prods. Liab. Litig.*, 2004 WL 2812095 (E.D.N.Y. December 3, 2004) (granting motion to sever non-product liability claims from product

---

<sup>5</sup> The same is true of the Micro Jewel II and Gem DR devices. Were a Complaint filed by a plaintiff who actually had a Micro Jewel II or Gem DR device implanted, such a case should be severed for the same reason that the non-Marquis field action device claims should be severed.



liability claims); *In re Diet Drugs Prods. Liab. Litig.*, 2004 WL 2095451, \*1 (E.D. Pa. Sept. 20, 2004) (severing misjoined unrelated claims and noting that unrelated claims “impede efficient administration” of MDL); *In re Merrill Lynch & Co., Inc. Research Rpts. Securities Litig.*, 214 F.R.D. 152, 155 (E.D. N.Y. 2003) (ordering severance of corporate claims from analyst claims); *In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019, 1038 (D. Minn. 1995) (Magnuson, J) (granting motion to sever state law claims).

Claims involving allegedly malfunctioning non-field action Marquis devices, or *any* device not subject to the February 2005 field action, do not arise from the same set of basic facts as claims involving Marquis devices subject to the February 2005 field action. The Marquis field action pertains to a potential for a battery shorting action in a small percentage of devices whose batteries were made by Medtronic between April 2001 and December 2003. The core allegation in the actions filed against Medtronic involving field action Marquis devices is that the devices allegedly contain a battery with this potential for sudden shorting and premature battery depletion. *See, e.g. Pearson* Complaint at ¶17, Exhibit D to Van Steenburgh Aff. Non-field action Marquis devices (or any device not subject to the February 2005 field action) do not contain a battery with this potential for premature depletion. Cases involving such devices will have different facts, witnesses, documents and proof. Discovery burdens and associated expenses relating to the non-field action Marquis device claims will expand and defeat one purpose of the MDL, which is to conserve the resources of the parties, their counsel and the judiciary. *See Transfer Order* at 2.

In sum, actions or claims, now or in the future filed, involving non-field action Marquis devices, such as the device in *Willis*, or non-Marquis devices, such as the device in *Lynn*, or any Gem DR or Micro Jewel II, must be severed.

**2. Remand of Claims Should Be Suggested**

Under 28 U.S.C. § 1407(a), the JPML may separate any claim, cross-claim, counter-claim, or third-party claim and remand any such claim to the district court of origin before the remainder of an action is remanded to the district. Under Rule 7.6(d) of the JPML Rules, “[t]he Panel is reluctant to order remand absent a suggestion of remand from the transferee district court.” 199 F.R.D. 425, 437.

In this case, the propriety of severance, coupled with Plaintiffs’ desire to prosecute claims relating to non-field action devices, mandates remand of those claims to the transferor courts in which they originated or will originate. Plaintiffs are entitled to pursue their claims; however, they should pursue those claims in the courts in which they originated or will originate. Remand, as permitted under the JPML Rules, is the procedure by which the Court can and should transfer those claims back to the court in which they originated. *See In re Zyprexa Prods. Liab. Litig.*, 2004 WL 2812095 \*5 (E.D.N.Y. Dec. 3, 2004) (severing claims and suggesting remand to JPML); *In re Merrill Lynch & co., Inc. Research Reports Securities Litig.*, 214 F.R.D. 152, 157 (S.D.N.Y. 2003) (same)

**C. Whether This MDL Should Include Any Matters Other Than Marquis Field Action Device Cases is Properly Before This Court**

Plaintiffs have suggested the issue of which devices are within the scope of the MDL is an issue for the JMPL. In concurrent proceedings before Magistrate Judge Boylan, Plaintiffs posit that the scope of MDL is a determination to be made by the JPML in the context of an objection to a conditional transfer order. *See* Plaintiff's Statement of Issues for January 30, 2006 citing *In re: Diet Drugs Prods. Liab. Litig.*, 2004 WL 2624851 (E.D. Pa. Nov. 18, 2004).

Any determination to strike, under Rule 12(f), to dismiss for lack of subject matter jurisdiction, or to sever and suggest remand is within this Court's power. *See In re Merrill Lynch & Co., Inc. Research Rpts. Securities Litig.*, 216 F.R.D. 76, 78 (S.D.N.Y. 2003) (striking assertions concerning stocks that fund at issue never held); *In re Potash Antitrust Litig.*, 1994 WL 1108312 (D. Minn. Dec. 5, 1994) (Erickson, MJ) (striking paragraphs not directed to events that lay in close proximity to acts forming basis of claim); *Zyprexa Prods. Liab. Litig.*, 2004 WL 2812095 (E.D.N.Y. December 3, 2004) (granting motion to sever non-product liability claims from product liability claims). Judge Bartle's order in the *Diet Drug* litigation does not mandate a different result. In fact, in a separate decision, Judge Bartle ordered that certain non-related claims be severed, noting that unrelated claims "impede efficient administration" of MDL. *See In re Diet Drugs Prods. Liab. Litig.*, 2004 WL 2095451, \*1 (E.D. Pa. Sept. 20, 2004) (severing misjoined unrelated claims)

In the particular *Diet Drug* order upon which Plaintiffs rely, the plaintiff sought remand from federal to state court and had objected to the conditional transfer order transferring his case to the MDL. With respect to the objection to the conditional transfer order, Judge Bartle noted in the footnote upon which the plaintiffs here rely, only that the plaintiff should have filed his objection with the JPML rather than the transferee court. 2004 WL 2624851 \*1, n.4.

Medtronic has not filed an objection to a conditional transfer order here. Nor does it argue that a particular case or claim should be remanded. Rather, it seeks dismissal of those claims where the plaintiffs have no standing and thus have no basis to prosecute a claim. Not only does this Court have the inherent power to determine whether it has subject matter jurisdiction under Article III, but the JPML has also indicated that this Court should determine those motions it deems appropriate. *See* Transfer Order, p. 2. Medtronic's motion is thus properly before this Court.

### **CONCLUSION**

For the reasons stated above, Defendant Medtronic, Inc. respectfully requests that the Court enter an Order striking all references to the Micro Jewel II Model 7223C, Gem DR Model 7271, and In Sync III Protect Model 7285, any Non-Marquis devices, and any Non-field action Marquis devices or, in the alternative, dismissing any claims relating to those devices, and an Order severing actions/claims involving any ICDs and/or CRT-Ds not identified as subject to the February 2005 action and suggesting remand of those cases/claims.

Respectfully submitted,

Dated: February 20, 2006

HALLELAND LEWIS NILAN  
& JOHNSON, P.A.

By S/Tracy J. Van Steenburgh  
Donald M. Lewis, Reg. No. 62844  
Tracy J. Van Steenburgh, Reg. No. 141173  
U.S. Bank Plaza South, Suite 600  
220 South Sixth Street  
Minneapolis, Minnesota 55402-4501  
(612) 338-1838

DEFENDANTS' LIAISON COUNSEL

Lori G. Cohen  
Jay B. Bryan  
Greenberg Traurig, LLP  
The Forum – Suite 400  
3290 Northside Parkway  
Atlanta, GA 30327  
(678) 553-2100

Stephen J. Immelt  
Hogan & Hartson, LLP  
111 South Calvert Street  
Baltimore, MD 21202  
(410) 659-2700

DEFENDANTS' CO-LEAD COUNSEL

# **EXHIBIT B**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

In re: MEDTRONIC, INC.,  
IMPLANTABLE DEFIBRILLATORS  
PRODUCTS LIABILITY LITIGATION

Multidistrict Litigation No.  
05-1726 (JMR/AJB)

**PRETRIAL ORDER**

The Judicial Panel on Multidistrict Litigation has transferred actions in the above-captioned matter to this Court for coordinated and consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407 as part of a nationwide litigation involving implantable defibrillators. Pursuant to this Court's jurisdiction over these actions, this Court hereby enters the following order:

1. Consolidation of Related Actions. Any other actions filed, whether filed directly in the United States District Court for the District of Minnesota or in any other United States District Court (whether by original filing or removal), that are related to this litigation are hereby consolidated into one action (the "Consolidated Action") for all pre-trial purposes, pursuant to Rule 42 of the Federal Rules of Civil Procedure and MDL Order dated December 8, 2005, under 28 U.S.C. § 1407(a).

2. Caption of Case. All orders, pleadings, motions and other documents served or filed in this Consolidated Action shall have the following caption:

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: MEDTRONIC, INC. IMPLANTABLE  
DEFIBRILLATORS PRODUCTS  
LIABILITY LITIGATION

MDL No. 05-1726 (JMR/AJB)

This Document Relates to ["All Actions" or  
specify by title and case number the individual  
applicable cases if the document relates to less  
than all of the consolidated cases.]

The original of this Order shall be filed by the Clerk and a copy thereof shall be filed in each subsequently filed or transferred action, which is related to and consolidated with this action. The Clerk of Court will maintain docket and case files under this caption, and pursuant to the procedures set forth in paragraph 3, below.

3. Docket and Filing Procedures.

- A. Master Docket and File. The Clerk will maintain a Master Docket and case file under the style set forth in paragraph 2, above. All orders, pleadings, motions and other documents will, when filed and docketed in the master case file, be deemed filed and docketed in each individual case to the extent applicable. The Master Docket is set up with the following parties: Plaintiffs' Lead Counsel, Plaintiffs' Liaison Counsel, Defendants' Lead Counsel and Defendants' Liaison Counsel. These parties will appear in the docket report. The defendants and plaintiffs from the other cases will be added as MDL - Notice Only party types, but will not appear on the docket report. See Attachment A (Memorandum re: CM/ECF FILING IN MEDTRONIC MDL 1726).



- B. Separate Dockets and Files. The Clerk will maintain a separate docket for each case removed or transferred to this Court. Each such case will be assigned a new case number in this Court.
- C. Captions and Separate Filing. Orders, pleadings, motions and other documents will bear the caption set forth in paragraph 2, above. If generally applicable to all consolidated actions, they shall include in their caption the notation that they relate to "ALL ACTIONS" and shall be filed and docketed only in the Master File. As set forth in paragraph 2, documents intended to apply only to particular cases will indicate in their caption the case number of the case(s) to which they apply and will be filed and docketed in the master case file and specified individual case file(s).
- D. Address, Number of Copies, and Electronic Filing. When filing documents relating to "ALL ACTIONS" with the Court, the parties will comply with the Court's requirements as to electronic filing and the documents shall be filed on the ECF system under the Master File or, if electronic filing is not possible, a signed original shall be sent to the Clerk, U.S. District Court, District of Minnesota, Suite 202, 300 South Fourth Street, Minneapolis, Minnesota 55415 for filing in the Master File. When filing documents relating to a particular case or cases, the documents shall be filed on the ECF system under both the Master File and the particular case, or, if electronic filing is not possible, one signed original shall be sent for the Master File and an additional copy for each particular case to which the matter related. For all dispositive motions and briefs, send two courtesy copies of memoranda and one copy of the attachments to Chambers (The Honorable James M. Rosenbaum, Chief Judge, U.S. District Court, District of

Minnesota, Room 15E, 300 South Fourth Street, Minneapolis, Minnesota 55415).

In addition, proposed orders should be sent in WordPerfect or Word to the Chambers e-mail box at rosenbaum\_chambers@mnd.uscourts.gov. If the motion is non-dispositive, mail two courtesy copies of memoranda and one copy of the attachments to Chambers ( The Honorable Arthur J. Boylan, Magistrate Judge, U.S. District Court, District of Minnesota, Room 202, 300 South Fourth Street, Minneapolis, Minnesota 55415) In addition, proposed orders should be sent in WordPerfect or Word to the Chambers e-mail box at boylan\_chambers@mnd.uscourts.gov .

E. Discovery Requests and Responses. Pursuant to Fed. R. Civ. P. 5(d), discovery requests and responses will not be filed with the Court except when specifically ordered by the Court or to the extent offered in connection with a motion.

F. Rules of Civil Procedure. All actions listed in the Schedule A attached to the JPML's Transfer Order of December 8, 2005, as well as any other actions subsequently transferred to or filed in this proceeding, shall be governed by the Federal Rules of Civil Procedure and the Local Rules for the District of Minnesota, including Local Rules 72.1 ("Magistrate Judge Duties") and 72.2 ("Review of Magistrate Judge Rulings").

4. Consolidation of Additional Actions. Any other action pending, subsequently filed or transferred to this Court, which arises out of the acts or transactions alleged in the Consolidated Action will be reassigned to this Court, and shall be consolidated herewith if and when they are called to the Court's attention.

5. Applicability of Order. This Order applies automatically to all actions listed in the Schedule A attached to the JPML's Transfer Order of December 8, 2005, as well as any other

actions subsequently transferred to or filed in this proceeding, without the necessity of future motions or orders. Should parties in any subsequently transferred or filed action object to the terms of this Order, they must do so within thirty (30) days of receipt of this Order from Plaintiffs' Liaison Counsel.

6. Service List. This Order shall be mailed to the persons named as Lead or Liaison Counsel in a separate order. Said counsel are required to forward a copy of the Order to other attorneys who have appeared in any action transferred to this court.. An updated and corrected service list shall be prepared as the litigation progresses. The Lead and Liaison Counsel for each party shall be responsible for establishing a service list and conferring with the Clerk of the Court to ensure that a Master Service List is established and kept current and which shall include all parties and counsel that may join this action.

7. List of Affiliated Companies and Counsel. To assist the Court in identifying any issues or matters of recusal or disqualification, counsel will submit to the Court, no later than thirty (30) days of receipt of this Order, a list of all companies affiliated with the parties and all counsel associated in the litigation.

8. List of Related Cases. Lead Counsel (whose identities will be set forth in a separate order) shall confer among themselves and jointly submit to the Court, no later than thirty (30) days of receipt of this Order, a list of all related cases pending in state and federal court and their current status, to the extent known.

9. Admission of Counsel. Attorneys admitted to practice and in good standing in any United States District Court are admitted as MDL attorneys in in this litigation. Association of local co-counsel is not required. All counsel are expected to familiarize themselves with the Local Rules of this Court, the American Bar Association's *Civil Discovery Standards*, as well as *The Manual for Complex Litigation 4<sup>th</sup>* (Federal Judicial Center 2004), which the Court and

parties may be called upon to refer to as a resource in the case management of this litigation. It is necessary to obtain a login and password to file electronically. Instructions regarding electronic filing and how to obtain a login and password in the District of Minnesota will be available on the website.

10. Organization and Responsibilities of Plaintiffs' Counsel.

- A. Plaintiffs' Lead Counsel Committee. The attorneys whom the Court will designate in a separate order as members of Plaintiff's Lead Counsel Committee will be members of and direct the work of the Plaintiff Steering Committee.
- B. Responsibilities of the Plaintiffs' Lead Counsel Committee. The attorneys on Plaintiffs' Lead Counsel Committee shall be responsible for coordinating the activities of Plaintiffs during pretrial proceedings and, in consultation and with the assistance of the Plaintiffs' Steering Committee, shall:
- i. Determine (after consultation with other members of Plaintiffs' Steering Committee and other co-counsel as may be appropriate) and present (in briefs, oral argument, or such other fashion as may be appropriate, personally or by a designee) to the Court and opposing parties the position of the Plaintiffs on all matters arising during pretrial proceedings;
  - ii. Coordinate the initiation and conduct of discovery on behalf of Plaintiffs consistent with the requirements of the Federal Rules of Civil Procedure relating to discovery or any other subsequent order of this Court;
  - iii. Conduct settlement negotiations on behalf of Plaintiffs, but not enter binding agreements except to the extent expressly authorized;

- iv. Delegate specific tasks to other counsel in a manner to ensure that pretrial preparation for the Plaintiffs is conducted effectively, efficiently, and economically;
- v. Enter into stipulations, with opposing counsel, necessary for the conduct of the litigation;
- vi. Prepare and distribute to the parties periodic status reports;
- vii. Maintain adequate time and disbursement records covering services as lead counsel;
- viii. Monitor the activities of co-counsel to ensure that schedules are met and unnecessary expenditures of time and funds are avoided;
- ix. Perform such other duties as may be incidental to proper coordination of Plaintiffs' pretrial activities or authorized by further Order of the Court; and
- x. Submit, if appropriate, additional committees and counsel for designation by the Court.

Counsel for Plaintiffs who disagree with Lead Counsel Committee (or those acting on behalf of lead counsel) or who have individual or divergent positions may present written and oral arguments, and otherwise act separately on behalf of their client(s) as appropriate, provided that in doing so they do not repeat arguments, questions, or actions of the Lead Counsel Committee.

C. Plaintiffs' Steering Committee. The Court will designate, by separate order, the members of the Lead Counsel Committee who will serve on Plaintiffs' Steering Committee.

The members of Plaintiffs' Steering Committee shall consult with the Plaintiffs'

Lead Counsel Committee in coordinating the Plaintiffs' pretrial activities and in planning for trial.

D. Plaintiffs' Liaison Counsel. The Court will designate Plaintiffs' Liaison Counsel by separate order. Plaintiffs' Liaison Counsel shall:

- i. **Service List:** Maintain and distribute to co-counsel and to Defendants' Liaison Counsel an up-to-date service list;
- ii. **Accept Service:** Receive and, as appropriate, distribute to co-counsel Orders from the Court and documents from opposing parties and counsel; and
- iii. **MDL Case File & Document Depository:** Maintain and make available to co-counsel and other Plaintiffs' counsel at reasonable hours a complete file of all documents served by or upon each party (except such documents as may be available at a document depository); and shall establish and maintain an electronically accessible document depository no later than February 15, 2006.

11. Defendant's Lead Counsel Committee. Lead Counsel Committee for Defendant shall be identified by separate order.

12. Privileges Preserved. No communication among Plaintiffs' Counsel or among Defendants' Counsel shall be taken as a waiver of any privilege or protection to which they would otherwise be entitled.

13. Service of Documents.

A. **Orders.** A copy of each Order will be provided to Defendant's Lead Counsel Committee and to the Plaintiffs' Lead Counsel Committee for distribution as

appropriate to other counsel and parties. To clarify the meaning of this paragraph, service through CM/ECF only goes to those who have filed a case and are in ECF. In cases that will be transferred here (but are not here yet), the new plaintiffs are not in the system yet. ECF can only notice those that are in the system at the time the document was filed. It therefore remains the responsibility of the lead or liaison counsel to affect service. While the Court can assist counsel with counsel's service list, at least in the beginning of this litigation, the list will contain parties and attorneys that are not in our system yet.

- B. Pleadings, Motions, and Other Documents.** Each member of the Plaintiffs' Lead Counsel Committee and Defendants' Lead Counsel shall be provided with one copy of each document served and/or filed by a party, including any and all attachments, to be delivered by electronic mail. Lead and Liaison Counsel shall also be provided with one non-electronic copy of each document served and/or filed by a party, including any and all attachments. Pursuant to Fed. R. Civ. P. 5, service on Plaintiffs' Lead Counsel Committee, including Liaison Counsel, constitutes service on other attorneys and parties for whom Counsel is acting, such service shall be deemed effective seven (7) days after service on Plaintiffs' Lead Counsel Committee.

14. Official Court Website. The Court has created and will maintain a website devoted solely to the Medtronic Implantable Defibrillators Products Liability Litigation, found at <http://www.mnd.uscourts.gov/>. Through the website, parties may access, as may be established, Court Orders, Court Minutes, Court Calendar, the Master Service List, Frequently Asked Questions, Court Transcripts, Court Docket, Current Developments and information as to Plaintiffs' Lead Counsel Committee and Liaison Counsel as well as Defendants' Lead Counsel.

Plaintiffs' Lead Counsel Committee and Liaison Counsel and Defendants' Lead Counsel shall confer with the Court regarding the content of the website.

15. Transcript Payment. The Official Transcript of all hearings shall be posted on the Medtronic Litigation website. The cost of the expedited Official Transcript shall be borne by the Plaintiffs and Defendants equally. Payment is to be made within fourteen (14) days of receipt of the Court Reporter's invoice.

16. Pleadings. Deadlines for answers or responses to the Complaints in all actions are hereby suspended except as ordered herein or until further Order of this Court.

17. Master Pleadings, Motions, and Orders.

A. Master Complaint.

It shall be the responsibility of Plaintiffs' Steering Committee to file,

- (1) a single master consolidated complaint containing allegations that would be suitable for adoption by reference in individual cases, and
- (2) a single master consolidated complaint containing allegations that would be suitable for adoption by reference in third party payor cases,

The master complaints shall not constitute the inception of a new "case or controversy" in this district and shall not supersede nor render moot the pending separate action that had been transferred to this district for pretrial proceedings by the MDL Panel. Rather, said master complaints shall be used as a device to facilitate ease of the dockets administration and to assist in identifying issues common to all of the cases centralized before this court. The allegations of the master complaints are not deemed automatically included in any particular case.



However, in order to avoid possible problems with statute of limitations or doctrines of repose, it shall be deemed (except to the extent a plaintiff hereinafter files an amended complaint disavowing such claims in theories or limits its claims in theories to those contained in an amended complaint) that, as of this date, for cases now pending in this court (or as of the date other cases are filed in, removed to, or transferred to this court) a motion is filed in each such case to amend the complaint to add any potentially applicable claims and theories from the master complaints not contained in the complaint actually filed in that case.

**B. Master Answers**

Defendant's lead counsel will file a master answers that will incorporate Defendant's defenses in law or fact to claims made against it in the various actions that are presently pending in this litigation. The answers will not attempt to provide a cross-reference to particular paragraphs or counts of the various complaints. The master answer(s) shall, however, cross-reference to particular paragraphs or counts in Plaintiffs' master complaint(s). The master answer shall in a "generic" manner admit or deny (including denials based on lack of information and belief) the allegations typically included in claims made against it as well as make such additional allegations as are appropriate to its defenses.

When so filed in MDL 1726, the master answers constitute an answer in each constituent case now pending or when hereafter filed in, removed to, or transferred to this court except to the extent the defendant later files a separate answer in an individual case.

**C. Refinement of Pleadings.**

It is anticipated that an amended, more specific complaint and answer may be

required before a case is scheduled for trial or remanded to a transferor court, but amendments of pleadings prior to that time should generally be avoided.

D. **Motions; Orders.**

A motion, brief, or response that has a potential effect on multiple parties (e.g., documents submitted in connection with a motion for partial summary judgment asserting that punitive damages are not recoverable with respect to [the product's use] in State A) will be deemed made in all similar cases on behalf of, and against, all parties similarly situated except to the extent such other parties timely disavow such a position. Additional motions, briefs, or responses addressed to such issues should not be filed or submitted by other parties except to the extent needed because of inadequacy of the original papers, to present unique facts, or because of a difference in positions. Orders resolving such motions will likewise be deemed as made with respect to all parties similarly situated unless the order indicates otherwise.

18. **Motions.** To avoid unnecessary litigation concerning motions, including motions relating to discovery disputes, counsel are directed to meet and confer before filing a motion. In any motion filed, counsel for the moving party must certify that a good-faith effort was made to resolve the dispute.

19. **Preservation of Evidence.** A separate order concerning preservation shall be entered by this court. The parties are hereby ordered to meet and confer for purposes of reaching an agreement on the language to be included in such order. To the extent that the parties are unable to agree, they are ordered to supply the court with a redline version of a proposed order containing the language agreed to and clearly identify which language is subject to disagreement between the parties and shall set forth clearly, the parties' proposals concerning the same. Said

redlined order setting forth the parties' competing proposals shall be filed no later than 4:30 p.m. on Wednesday, January 18, 2006. The parties may also supply the court with an informal letter brief not to exceed 2 pages in length.

20. Protective Order. A separate order concerning protective order language shall be entered by this Court. The parties are hereby ordered to meet and confer for purposes of reaching an agreement on the language to be included in such order. To the extent that the parties are unable to agree, they are ordered to supply the Court with a redline version of a proposed order containing the language agreed to and clearly identifying which language is subject to disagreement between the parties and shall set forth clearly, the parties' proposals concerning the same. Said redlined order setting forth the parties' competing proposals shall be filed no later than 4:30 p.m. on Wednesday, January 18, 2006. The parties may also supply the Court with an informal letter brief not to exceed 2 pages in length.

21. Status Conferences. The Court will convene Status Conferences in its discretion. Counsel for each side shall meet and confer in advance of each Status Conference and submit to the Court a joint Agenda and Status Conference report listing matters to be considered by the Court at the Status Conference.

Status Conferences shall be regularly scheduled by the Court to permit substantial advance notice to all parties. Except as otherwise provided herein, and to accommodate the schedules of the Court and the parties, all argument or hearing on any motion will be scheduled to coincide with calendared Status Conferences. Any hearing or oral argument deemed necessary by the Court on motions that require a ruling on an expedited basis will be scheduled with notice of at least five business days. If circumstances warrant, the Court may shorten a notice period.

The next Status Conference is scheduled for Thursday, February 16, 2006, at 9:00 a.m.,

in Courtroom 15E, United States Courthouse, 300 South Fourth Street, Minneapolis, Minnesota. At the next and all future Status Conferences, the parties are to provide the Court, within three business days before each Status Conference, an agreed upon agenda for the conference, and to provide a brief—one to two paragraph—summary of the party positions as to any disputed issues.

Further, unless otherwise ordered herein, it shall be the intent of the Court to meet in chambers with lead counsel for Plaintiffs and lead counsel for Defendants 45 minutes before each Status Conference.

Continuing in March 2006, and every month thereafter, unless otherwise ordered by this Court, Status Conferences shall be held on the third Thursday of each month at 9:00 a.m., at the United States Courthouse in Minneapolis, 300 South Fourth Street, Minneapolis, Minnesota.

22. Timing.

- A. Plaintiffs' Master Complaint(s) shall be served and filed on or before February 15, 2006.
- B. Defendant's Master Answer shall be served or filed on or before March 15, 2006.  
Defendant shall also serve and file any early dispositive motions seeking judgment on the pleadings and/or summary judgment by said date.
- C. Discovery on the defenses identified in the Defendant's Master Answer and dispositive motions shall be completed by May 1, 2006. The parties are generally aware of the Defendant's contentions concerning preemption and other defenses and as such, the Plaintiffs may commence discovery on those issues immediately and need not wait for the service of the Master Answer or other pleadings.
- D. Plaintiffs' responsive brief to Defendant's dispositive motions shall be served and filed on or before May 15, 2006.
- E. Defendant's reply brief shall be served and filed on or before June 1, 2006.

F. A hearing on any such motions filed shall be held before the Honorable Chief Judge James M. Rosenbaum at a date and time to be determined.

23. Discovery Limitations.

A. No more than 20 interrogatories (counted in accordance with Federal Rules of Civil Procedure 33(A)) shall be served by any party.

B. No more than 6 depositions, including depositions noticed pursuant to Rule 30(B)(6). When agreed to between the parties, the depositions may exceed the 7 hour time limit imposed under FRCP 30(D)(2). Categories of document requests may include but not be limited to the following:

- i. All submissions made to the FDA concerning the devices at issue.
- ii. All communications to the FDA concerning the devices at issue.
- iii. All adverse event reporting documents regarding the devices at issue
- iv. All documents and communications referring to the at issue devices' pre-market approval process and any supplementations to the pre-market approval.

C. The Magistrate Judge shall periodically convene informal telephone conferences designed to address any discovery disputes that may arise. The initial conference shall be scheduled to commence at 9:00 AM on Monday January 30, 2006. Said conferences shall be limited to 30 minutes. The parties shall submit letters, not exceeding two pages in length, identifying issues which the parties wish the court to address. Said letters shall be delivered to the Magistrate Judge's chambers e-mail no later than 1:00 PM on the business day prior to the conference. Counsel

shall agree between themselves on who will be responsible for coordinating the telephone conference.

24. Future Scheduling Conferences. Immediately upon the parties being served with the Court's order on the defendant's dispositive motions, they shall immediately notify the undersigned Magistrate Judge for purposes of convening a scheduling/case management conference as needed given the Court's determination and order on said dispositive motion.

Dated: January 20, 2006

s/Arthur J. Boylan  
ARTHUR J. BOYLAN  
Magistrate Judge of United States District Court

**MEMORANDUM re CM/ECF FILING IN MEDTRONIC MDL 1726**

**TO ALL COUNSEL in MEDTRONIC MATTERS**

---

**CM/ECF stands for Case Management, Electronic Case Files**

Before attempting electronic filing in these matters, please take time to read the U.S. District Court, District of Minnesota's Electronic Case Filing Civil ECF User's Manual and Civil ECF Procedures Guide posted on the U.S. District Court of Minnesota's website (<http://www.mnd.uscourts.gov/>). Once the website is accessed (<http://www.mnd.uscourts.gov/>), click on "Electronic Case Filing" on the left-hand side of the home page. Please review the User's Manual and Procedures Guide before filing a document. Please feel free to call the ECF helpdesk if you have questions (612-664-5155). Please make certain that the attorney filing the document(s) has seen and approved of the document(s) before undertaking filing as you are using the attorney's bar number, login and password to file.

➤ **Obtaining an ECF Login Name and Password**

The Court's main website contains information on how to register for an ECF login and password. After accessing the website, click on "Registration form for e-filing-MDL attorneys" located in the Forms link on the left-hand side. To access the court's live ECF website, select Live ECF Link on the left-hand side of the Court's home page. Adding a second (or third) e-mail address may be done at the time of registration by listing the additional e-mail address(es) on the "additional e-mail" line on the original registration form. Under "Electronic Case Filing," there are directions as to how to add a secondary e-mail address if you are already registered.

- A separate PACER (Public Access to Court Electronic Records) login and password is necessary. It is likely that you, or your firm, already has a PACER account. If not, a PACER account can be established by contacting:

PACER SERVICE CENTER  
P.O. Box 780549  
San Antonio, TX 78278  
(800) 676-6856  
<http://pacer.psc.uscourts.gov/>

- **IMPORTANT NOTE:** The court's ECF system gets bogged down with the many documents being uploaded, especially on Friday afternoons. It is suggested that you begin early (if you have many attachments you may want to begin by **11:30 a.m., Central Time**). If it is a simple filing without attachments, you can begin as late as 2:00 p.m., CT). If there are problems encountered, beginning early will help ensure that your filing will be timely. If you have technical problems, please contact the Court's Help Desk.\*

- Please refer to MD 1726 and relevant Pretrial Orders for electronic filing questions. In Section A. Master Docket and File., the Master Docket is set up with the following parties: Plaintiffs' Lead Counsel, Plaintiffs' Liaison Counsel, Defendants' Lead Counsel and individual Defendants. These parties will appear on the docket report. Plaintiffs from the other cases will be added as MDL-Notice Only party types, but will not appear on the docket report. All parties can be queried by selecting the Party when using CM/ECF Query. When filing documents in the Master Docket, select the appropriate party. If the filer is a member of the Plaintiffs' Liaison Counsel, select Plaintiffs' Liaison Counsel, for example. If the filer is a plaintiff in one of the individual cases, select the appropriate party, but note that the party type in the Master Docket case will be MDL-Notice Only. In addition, all parties must file a Notice of Appearance in the Master Docket after their initial filing in an individual case. Also see section D. Address, Number of Copies and Electronic Filing. for specific instructions. When filing documents relating to a particular case or cases, the documents shall be filed on the ECF system under both the Master Docket and the particular case(s).
- All documents filed in the USDC's CM/ECF must be in "PDF" format (.pdf). The most widely used program that can convert from Word and/or Word Perfect to .pdf, is Acrobat. If you do not know how to change a document from Word to .pdf and move it to your export file, ask your Help Desk for assistance or our website for assistance.
- Each filing/upload of documents **cannot** be larger than 2MB. If a document or attachments exceed 2MB, divide it/them into appropriate amounts and use page numbers for each section and file as separate attachments. (E.g.: File Attachment A, part 1 of 3, pp. 1 – 50; then file as separate attachment, Attachment A, part 2 of 3, pp. 51- 100; and also file as separate attachment, Attachment A, part 3 of 3, pp. 101 – 149.) When you create your Word/WP document in preparation to file it and/or when you convert it to a .pdf, your computer can show the size of the document/PDF.
- After e-filing your document(s), if appropriate, e-mail the judge the proposed order(s) only. **Proposed orders must be converted to WordPerfect ("WP") or Word format prior to sending them to the judge.** DO NOT send other papers to the judge's e-mail address. Reference the case or cases in the subject line and body of the e-mail if it is only a few cases. If the proposed order refers to all cases, state so. If the filing relates to many, but not all cases, put a list of cases to which the proposed order applies in the text of the e-mail and the moving party(ies)'s name(s) for reference. The email address is [rosenbaum\\_chambers@mnd.uscourts.gov](mailto:rosenbaum_chambers@mnd.uscourts.gov)
- After you complete your filing and obtain your proof of filing page, please make certain you **logout** of the ECF system.
- Note: Do not be alarmed if you see "CASE CLOSED" on an e-mail docket distribution from the court. It is only an internal matter for the court and does not affect the current docket in that case.



\*If you encounter problems, please call **Court's Help Desk line 1-866-325-4975**. If you reach a voice mailbox, leave a clear message including your name and telephone number. If you cannot complete your filing electronically, please see section L. Technical Failure in the Civil ECF Procedures Guide.

If you inadvertently file a document in the *wrong case*, please refer to Section L. Correcting Docket Entries on page 20 of the Court's Civil ECF Procedures manual. However, if your *document* is wrong but filed in the correct case, you will have to file an amended version of your document.

New complaints, summonses & civil cover sheets cannot be filed and served using CM/ECF at this time, but they can be e-mailed to the clerk for processing and posting to CM/ECF. The email address for new cases is [newcases@mnd.uscourts.gov](mailto:newcases@mnd.uscourts.gov).

If a filer does not know whether another party is a registered ECF user, they can go onto CM/ECF, select "Utilities," then "Mailing Information for a Case" and enter the case number and the information will appear.

Filing deadline shall be 11:59 p.m. Central Time. If your document goes through after Midnight p.m., it will be considered filed on the following day.

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA  
ELECTRONIC FILING REGISTRATION FORM FOR MDL ATTORNEYS**

This form is used by attorneys in MDL matters to register for an account on the District of Minnesota Electronic Filing System (ECF). Registered attorneys will have privileges to electronically submit documents and to receive electronic service of filings. By registering, attorneys consent to receiving electronic notice of filings through ECF. Only attorneys may register for an ECF account. The following information is required for registration:

**PLEASE TYPE**

Mr./Mrs./MS. (circle one)

First Name: \_\_\_\_\_ Middle Name: \_\_\_\_\_

Last Name: \_\_\_\_\_ If appropriate, circle one: Senior /Junior /II /III

Federal/State Court admission (what state): \_\_\_\_\_ Bar ID Number: \_\_\_\_\_

Firm Name: \_\_\_\_\_

Firm Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Voice Telephone Number \_\_\_\_\_ Fax Number: \_\_\_\_\_

Internet Mail Address: \_\_\_\_\_

MDL action - indicate case number: \_\_\_\_\_

By submitting this registration form, the undersigned agrees to abide by all Court rules, orders and policies and procedures governing the use of the electronic filing system. The undersigned also consents to receiving notice of filings pursuant to Fed. R. Civ. P. 5(b) and 77(d) through the Court's electronic filing system. The combination of user ID and password will serve as the signature of the attorney filing the documents. Attorneys must protect the security of their passwords and immediately notify the court if they learn that their password has been compromised.

\_\_\_\_\_  
Signature of Attorney Registrant

\_\_\_\_\_  
Date

E-mail the completed form to:

[ecfhelpdesk@mnd.uscourts.gov](mailto:ecfhelpdesk@mnd.uscourts.gov) with Subject line: Attention: ECF Registration  
- MDL

# EXHIBIT C

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: MEDTRONIC, INC.,  
IMPLANTABLE DEFIBRILLATORS  
PRODUCTS LIABILITY LITIGATION.

Multidistrict Litigation No.  
05-1726 (JMR/AJB)

---

**ORDER**

On Monday, January 30, 2006, the Court held an informal telephone conference in the above captioned litigation. Appearances were made by Plaintiff and Defense lead counsel. The Court during the conference considered a number of matters including the following:

1. Defendants requested that the Court consider amending the Pretrial Order of January 20, 2006, concerning the requirement that Medtronic notify patients or their counsel if Medtronic intended to conduct destructive testing on any device described in the Order that had been returned to Medtronic after being ex-planted from a patient. The Court has considered Medtronic's request in this regard and declines to amend the Order, and to the extent that the request is considered as a motion, the motion is **denied**.
2. Medtronic seeks to expand the time within which to file a reply brief from 15 days to 30 days. This motion is **denied**.
3. Plaintiffs seek a more detailed discovery schedule that addresses the time frame within which Defendants must serve objections to Plaintiff's first set

of written discovery. The Court has considered said request and makes the following Order:

- a. Plaintiffs must file their first set of written discovery on or before February 1, 2006.
- b. Defendants must serve their objections no later than February 13, 2006.
- c. Parties must complete good faith meet and confer on said objections by February 17, 2006.
- d. Any motion to compel or for protective order must be filed by February 21, 2006.
- e. Any oppositions to said motions must be filed by February 28, 2006. The undersigned Magistrate Judge will determine whether oral argument would be desirable and if so, will schedule a hearing as soon as possible thereafter.
- f. Defendant shall produce non-objectionable documents on a rolling basis beginning no later than March 3, 2006.
- g. Defendant shall provide substantive answers to non-objectionable written discovery no later than March 3, 2006.
- h. Defendant shall produce a supplemental privilege log no later than March 10, 2006.

Date: January 30, 2006

s/ Arthur J. Boylan  
ARTHUR J. BOYLAN  
United States Magistrate Judge

MEMORANDUM

A number of other matters were discussed in the informal telephone conference conducted on January 30. Many of those issues have been resolved between the parties and will be subject to stipulations which will be hereafter filed together with proposed orders for the Court's signature. The Court considered Plaintiffs' request for an expedited motion schedule for interim relief but does not believe that an order setting forth the schedule is necessary at this time. The Court likewise considered Plaintiffs' suggestions for mandatory mediation discussions. No court ordered mediation discussions are going to be scheduled at this time. The Court encourages the parties to continue any discussion between them that leads to resolution of any issues that may arise in this litigation.

AJB

# EXHIBIT D

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

In re: Medtronic, Inc. Implantable Defibrillators  
Products Liability Litigation

MDL No. 05-1726 (JMR/AJB)

\_\_\_\_\_  
This Document Relates to All Actions

**PLAINTIFFS' FIRST SET OF INTERROGATORIES REGARDING PREEMPTION**

PLEASE TAKE NOTICE that plaintiffs, pursuant to Rules 33 of the Federal Rules of Civil Procedure and in accordance with the Order of United States Magistrate Judge Arthur J. Boylan dated January 30, 2006, hereby request that defendant provide substantive answers to written discovery as requested in the following Interrogatories within 30 days of service, but in no event later than March 3, 2006, and request that the Interrogatories be answered separately, fully and under oath, and sent to the offices of Daniel E. Gustafson at Gustafson Gluek PLLC, 650 Northstar East, 608 2nd Avenue South, Minneapolis, MN 55402 or Charles S. Zimmerman at Zimmerman Reed P.L.L.P., 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402 or at such other mutually acceptable time and place as agreed by the parties.

**DEFINITIONS**

The following definitions shall apply to each of the Interrogatories set forth below and are deemed to be incorporated in each of the requests:

1. "And" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive; and "any" as used herein means "each and every" as well as "any one."



2. "Communication(s)" refers to the oral or written transfer of data, facts, ideas, inquiries, opinions or other information.

3. "Defendant," "You" and "Your" refers to Medtronic, Inc., and also includes every predecessor in interest of Medtronic, Inc., including but not limited to each company's successor(s) in interest, and every company affiliated with each such company by common ownership or control, as well as all board members, officers, employees, agents and servants of any Defendant and any other natural person or corporate entity acting for or on a Defendant's behalf.

4. "Document" is used in the broadest sense consistent with the definitions used in the Federal Rules of Civil Procedure including, but not limited to any chart, paper, graph, sketch, drawing, photograph, microfilm, index, data, sheet, diary, forecast, account, analysis, minutes or records of meetings or conferences, appraisal, summary, contract projection, press release, or any other written, recorded, transcribed, punched, taped, filmed or graphic matter, however produced or reproduced, within the possession, custody or control of any Defendant.

5. "Identify" when used in reference to an individual person shall mean to state his full name and present or last known address, his present or last known position and business affiliation, and his position and business affiliation at the time in question. When used in reference to a corporation or business entity, state its present or last known address.

6. "Identify" when used in reference to a document shall mean and include the name and address of the custodian of the document, the location of the document, and a general description of the document, including: (1) the type of the document (*i.e.*, correspondence, memorandum, facsimile, etc.); (2) the general subject matter of the document; (3) the date of the

document; (4) the author of the document; (5) the addressee of the document; and (6) the relationship of the author and addressee to each other.

7. "Identify" when used in reference to an oral Communication shall mean to: (1) state its date and the general subject matters discussed; (2) identify each participant; and (3) identify each document referring or relating to, or recording or reflecting, the meeting.

8. "Implantable cardioverter defibrillator," "ICD," "cardiac resynchronization therapy defibrillator," and/or "CRT-D," refers to Defendant's defibrillator brand names: Micro Jewell II, GEM DR, InSync I/II/III Marquis, Marquis VR/DR, and Maximo VR/DR.

9. "Person" means natural person, group of natural persons acting as individuals, group of natural persons acting in a collegial capacity (*e.g.*, as a committee, board of directors, etc.) entity, including without limitation sole proprietorship, firm, association, company, partnership, joint venture corporation or division or subsidiary thereof, trust, estate, and other incorporated or unincorporated business and other social, legal, or governmental entity of any kind.

### **INSTRUCTIONS**

1. The Defendant shall respond to each Interrogatory separately. All information is to be divulged which is in the possession or control of you, your attorneys, investigators, agents, employees and other representatives of you or your attorney.

2. Where an individual Interrogatory calls for an answer which involves more than one part, each part of the answer should be clearly set out so that it is understandable. If any of these Interrogatories cannot be answered in full, please answer to the extent possible and submit any supplemental information at a later date.

3. If you determine that any question is not applicable and, consequently, deserves no answer, state in detail why you contend it is not applicable.

4. If you lack the information necessary to answer any of the Interrogatories, please describe the specific efforts made by you or anyone on your behalf to ascertain the information and state as definitely as possible when you anticipate obtaining information supplementing your response.

5. If you object to fully identifying a document or oral Communication because of a privilege, you must nevertheless provide the following information, unless divulging the information would disclose the privileged information: (1) the nature of the privilege claimed (including work product); (2) if the privilege is being asserted in connection with a claim or defense governed by state law, the state privilege rule being invoked; (3) the date of the document or oral Communication; (4) if a document: its type (correspondence, memorandum, facsimile, etc.), custodian, location, and such other information sufficient to identify the document for a subpoena *duces tecum* or a document request, including where appropriate the author, the addressee, and, if not apparent, the relationship between the author and addressee; (5) if an oral Communication: the place where it was made, and if not apparent, the relationship of the persons present to the declarant; and (6) the general subject matter of the document or oral Communication.

6. If you object to an Interrogatory as vague and ambiguous, specify how the Interrogatory is susceptible to multiple meanings and answer the Interrogatory in accordance with your best good-faith interpretation of the information called for by the Interrogatory.

7. If the original document was destroyed, state the date and reason for or circumstances under which it was destroyed.

8. If any Interrogatory may be answered fully by a document, the document may be attached in lieu of an answer if the document is marked to refer to the Interrogatory to which it responds.

9. If you rely upon documents in answering these Interrogatories, please identify each and every such document by bates number.

10. In accordance with Federal Rule of Civil Procedure 26(e), you are under a continuous obligation to supplement your answers to these interrogatories as new or more accurate information becomes known to you.

### **INTERROGATORIES**

#### **INTERROGATORY NO. 1.**

State the name, job title, address and phone number of each person answering these Interrogatories, supplying information, or assisting in any way with the preparation of the answers to these Interrogatories and provide the specific nature and substance of the knowledge that you believe the person(s) identified in your response may have.

#### **INTERROGATORY NO. 2.**

Identify each and every current and former employee, agent, officer or director with responsibility for the development; regulatory approval; and marketing and promotion of the ICDs and/or CRT-Ds, and for each person, state what his or her responsibilities are or were, whether such person is still employed by the Defendant, and for those who are no longer employed, his or her last known address.

#### **INTERROGATORY NO. 3.**

Identify each and every current and former employee, agent, officer or director associated with Defendant's "Safety Surveillance," "Clinical Research," "Public Relations," "Regulatory Affairs," and "Marketing Units," product teams for ICDs and/or CRT-Ds, and for each such

person, state what his or her duties are and/or were, whether such person is still employed by the Defendant, and for those who are no longer employed, his or her last known address.

**INTERROGATORY NO. 4.**

Identify each and every current and former company, operating division, department and office owned, operated and/or maintained by Defendant which has and/or had responsibilities with regard to the design, testing, approval, marketing, promotion, manufacturing and/or labeling of ICDs and/or CRT-Ds, including all companies or third parties retained by Defendant in connection with the design, development, testing, approval, marketing, and/or recall of ICDs and/or CRT-Ds. For each identified, state the type of each such entity and/or operation (*i.e.*, department, division, etc.), describe the business operations of each, the location where documents and/or records are stored and/or maintained for each, and for any such entity and/or operation which is no longer in existence, state which entity and/or operation has taken over the defunct's entity's responsibilities with regard to ICDs and/or CRT-Ds.

**INTERROGATORY NO. 5.**

Identify every individual with whom Defendant had contact at the FDA and/or any Foreign Government Regulatory Agency in connection with or related to ICDs and/or CRT-Ds.

**INTERROGATORY NO. 6.**

State each and every warranty, representation, or promotional statement or Communication that Defendant, or any of their salesmen or sales agents made between the dates of January 1, 1996 and the present about the advantages of implanting an ICD or CRT-D into a patient.

**INTERROGATORY NO. 7.**

State the name, current address (or last known address if current address is unknown), telephone number, position with the Defendant, Defendant Employee No., and present employer of each and every employee of Defendant who reported or were notified, orally or in writing, of any alleged problems or defects with the design, manufacture, assembly, inspection, testing, and/or quality control of any ICD and CRT-D models and give the respective dates and substance of each such report, who such report was from and addressed to, and whether or not said report resulted in a recall or attempted recall of the specific ICD and CRT-D models.

**INTERROGATORY NO. 8.**

Describe in detail each stage of the development of each ICD and CRT-D model, making specific reference to the name of the process and the particular engineering diagrams which are applicable to each process. In this regard, please attach a copy of all memoranda and documents pertaining to the manufacture of ICD and CRT-D models that were provided to the FDA as part of the approval process.

**INTERROGATORY NO. 9.**

State in detail the facts/events that caused Defendant to issue a statement in April 2004 that it was voluntarily advising physicians about defective high voltage capacitors that may occur in a subset of the ICD and CRT-D models.

**INTERROGATORY NO. 10.**

State in detail the facts/events that caused Defendant to issue a statement in February 2005 that it was voluntarily advising physicians about a potential battery shorting mechanism that may occur in a subset of the ICD and CRT-D models.

**INTERROGATORY NO. 11.**

Set forth in detail when Defendant first became aware that potential battery shorting and/or defective high voltage capacitors may occur in ICD and CRT-D models and the steps undertaken by Defendant to determine what was causing the problems in the ICD and CRT-D models, and what steps Defendant took in response to the potential shorting mechanism and defective high voltage capacitor mechanism. Include in your answer the identity of all persons with knowledge of the defective high voltage capacitor problem prior to April 2004 and the battery shorting mechanism prior to February 2005 and the persons with knowledge of the steps taken by Defendant in response to the problems; their complete name address and position with the company if any; what the person knew or knows and when they first became aware of it; any documents generated by that person regarding the problems and all documents relating to the problems; what, if any, approvals Defendant sought from the FDA to correct the “potential shorting problem” and defective high voltage capacitor problem and what, if any, information was provided to the FDA as part of this process.

**INTERROGATORY NO. 12.**

Set forth in detail whether Defendant sold, distributed and/or marketed any devices with potential shorting mechanisms and/or capacitor defects during the time period that Defendant was seeking FDA approval of product changes to correct the “potential shorting problem” and defective high voltage capacitor problem. Include in your answer: what marketing efforts were undertaken by Defendant to sell, distribute and/or market the devices with potential shorting mechanisms during the time period that Defendant was seeking to correct the potential problems; all persons involved in the marketing, sales and/or distribution of the potentially effected devices; and all documents related to this.

**INTERROGATORY NO. 13.**

Set forth in detail why Defendant submitted a request for a PMA and/or received a supplemental PMA from the FDA for approval of changes regarding the following Medtronic defibrillator brand names: Micro Jewell II, GEM DR, InSync I/II/III Marquis, Marquis VR/DR, and Maximo VR/DR.

**INTERROGATORY NO. 14.**

Set forth in detail Defendant's standard operating procedures for, complaint handling, conducting failure investigation, taking corrective and preventive action, document control, methods for design, and validation of ICDs and CRT-Ds.

**INTERROGATORY NO. 15.**

Set forth in detail Defendant's procedures for statistical analysis of complaints and component rejects with respect to the ICDs and CRT-Ds.

**INTERROGATORY NO. 16.**

Describe in detail Defendant's Communications with component suppliers regarding production, specification of capacitors, and batteries for ICDs and CRT-Ds.

**INTERROGATORY NO. 17.**

Describe in detail which batteries and capacitors were utilized by Medtronic in its ICDs and CRT-Ds from 1996 through the present.

**INTERROGATORY NO. 18.**

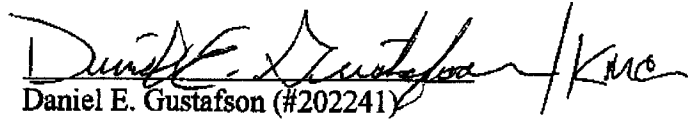
Describe in detail Communications between Defendant and the FDA regarding the models involved in the recalls and alert actions, including: descriptions of product testing; failure investigations; manufacturing and quality control actions; and actions that were instituted to quarantine and destroy involved products.



**INTERROGATORY NO. 19.**

Describe in detail Defendant's standard operating procedures and all revisions for Defendant's medical device reporting from 1996 through the present.

Dated: February 1, 2006



Daniel E. Gustafson (#202241)  
**Gustafson Gluek PLLC**  
650 Northstar East  
608 Second Avenue South  
Minneapolis, MN 55402  
Tel: (612) 333-8844  
Fax: (612) 339-6622  
Email: [dgustafson@gustafsongluek.com](mailto:dgustafson@gustafsongluek.com)

Charles S. Zimmerman (#102254)  
**Zimmerman Reed P.L.L.P.**  
651 Nicollet Mall, Suite 501  
Minneapolis, MN 55402  
Tel: (612) 341-0400  
Fax: (612) 341-0844  
Email: [csz@zimmreed.com](mailto:csz@zimmreed.com)

***Plaintiffs' Co-Lead Counsel***

# **EXHIBIT E**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

In re: Medtronic, Inc. Implantable Defibrillators  
Products Liability Litigation

MDL No. 05-1726  
(JMR/AJB)

\_\_\_\_\_  
This Document Relates to All Actions

**PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION  
OF DOCUMENTS AND THINGS FOR INSPECTION AND COPYING**

**PLEASE TAKE NOTICE** that plaintiffs, pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and in accordance with the Order of United States Magistrate Judge Arthur J. Boylan dated January 30, 2006, hereby request that Defendant, Medtronic, Inc., produce and permit plaintiffs' counsel to inspect and copy those documents and things specified herein, which are in the possession, custody or control of the Defendant, as soon as such documents are available, but in no event later than March 3, 2006, at the offices of Daniel E. Gustafson at Gustafson Gluck PLLC, 650 Northstar East, 608 Second Avenue South, Minneapolis, MN 55402 or Charles S. Zimmerman at Zimmerman Reed P.L.L.P., 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402 or at such other mutually acceptable time and place as agreed by the parties.

**DEFINITIONS**

The following definitions shall additionally apply to each of the requests for production set forth below and are deemed to be incorporated in each of the requests:

1. "Communication" shall mean any oral or written transmittal and/or receipt of facts, information, thoughts, inquiries, opinions, including, without limitation, meetings, conversations in person, telephone conversations, records of conversations or messages, telegrams, telexes, facsimile transmissions, electronic mail transmissions, letters, reports, memoranda, formal statements and press releases, and newspaper stories. References to

Communications with business entities shall be deemed to include all officers, directors, employees, agents, attorneys, accountants, consultants, independent contractors, or other representatives of such entities.

2. “Defect” when used in any request refers to, *inter alia*, “rapid battery depletion due to shorting action,” “potential for rapid battery depletion due to shorting action,” or defects with respect to high voltage capacitors.

3. “Defendant,” “You” and “Your” refers to Medtronic, Inc., and also includes every predecessor in interest, successor(s) in interest, and every company affiliated with each such company by common ownership or control, as well as all board members, officers, employees, agents and servants of Defendant and any other natural person or corporate entity acting for or on Defendant’s behalf.

4. “Document” is used in the broadest sense consistent with the definitions used in the Federal Rules of Civil Procedure and include, but is not limited to, any chart, paper, graph, sketch, drawing, photograph, microfilm, index, data, sheet, diary, forecast, account, analysis, minutes or records of meetings or conferences, inter-office memoranda, communications, appraisal, summary, contract projection, press release, or any other written, recorded, transcribed, punched, taped, filmed or graphic matter, however produced or reproduced, within the possession, custody or control of Defendant.

5. “FDA” refers to the Food and Drug Administration of the United States, and any person, employee, agent or representative acting on its behalf.

6. “Identify” when used in reference to an individual person shall mean to state his or her full name and present or last known address, his or her present or last known position and business affiliation, and his or her position and business affiliation at the time in question. When used in reference to a corporation or business entity, state its present or last known address.

7. “Identify” when used in reference to a Document shall mean and includes the name and address of the custodian of the Document, the location of the Document, and a general description of the Document, including where possible: (1) the type of the Document (*i.e.*, correspondence, memorandum, facsimile.); (2) the general subject matter of the Document; (3) the date of the Document; (4) the author of the Document; (5) the addressee of the Document; and (6) the relationship of the author and addressee to each other.

8. “Identify” when used in reference to an oral Communication shall mean to: (1) state its date and the general subject matters discussed; (2) identify each participant; and (3) identify each Document referring or relating to, or recording or reflecting, the Communication.

9. “Implantable cardioverter defibrillator,” “ICD,” “cardiac resynchronization therapy defibrillator,” and/or “CRT-D,” refers to Defendant’s defibrillator brand names: Micro Jewell II, and GEM DR, InSync I/II/III Marquis, Marquis VR/DR, Maximo VR/DR.

10. “MHRA” refers to the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, and any person, employee, agent or representative acting on its behalf.

11. “Person” means natural person, a group of natural persons acting as individuals, a group of natural persons acting in a collegial capacity (*e.g.*, as a committee, board of directors), an entity, including without limitations sole proprietorship, firm, association, company, partnership, joint venture corporation or division or subsidiary thereof, trust, estate, and other incorporated or unincorporated business.

12. “Relating to” means and includes: with respect to, concerning or in connection with, referring to, regarding, substantiating, purporting, embodying, establishing, identifying, listing, evidencing, stating, comprising, connected with, memorializing, recording, commenting upon, responding to, showing, describing, analyzing, reflecting, representing,

constituting, supporting, contradicting, dealing with, embodying, or explaining, whether in whole or in part.

### **INSTRUCTIONS**

1. Defendant shall respond to each request separately. All responsive non-privileged documents shall be produced which are in Your possession or in the possession of Your attorneys, investigators, agents, employees and other representatives of You and/or Your attorney.

2. “And” and “or” shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive; and “any” as used herein means “each and every” as well as “anyone.”

3. If any of these requests cannot be complied with in full, please produce as many documents as possible and produce any supplemental documents at a later date.

4. If You determine that any request is not applicable and, consequently, deserves no response, state in detail why You contend it is not applicable.

5. If You determine that You cannot locate the requested documents, please describe the specific efforts made by You or anyone on Your behalf to locate the requested documents and state as definitely as possible when You anticipate obtaining and producing the requested documents and supplementing Your response.

6. In responding to these requests, You are required to produce documents not only within Your personal possession or control, but any documents in the possession or control of Your attorneys, investigators, adjusters, insurance carriers, representatives, agents, or anyone acting on Your behalf or their behalf.

7. If You are unable to respond to these requests in full after exercising due diligence to secure the requested documents, respond as completely as possible and then

explain the reason You are unable to respond more fully, and state the name, address and telephone number of any person or persons able to supply the documents requested.

8. If You object to any request, specify the part which You object to and the basis for the objection and respond to the remaining part of the request pursuant to Federal Rule of Civil Procedure 34.

9. If You object to a request as vague and ambiguous, specify how the request is susceptible to multiple meanings and respond in accordance with Your best good-faith interpretation of the information called for by the request.

10. In accordance with Federal Rule of Civil Procedure 26(e), You are under a continuous obligation to supplement Your responses to these document requests.

#### **RELEVANT TIME PERIOD**

1. Unless otherwise indicated, these requests seek Documents created, used during, or Concerning the time period January 1, 1996 through the present, including all Documents Concerning, in whole or in part, such period, or events or circumstances during such period, even though dated, prepared, generated, or received prior or subsequent to that period.

#### **REQUESTS FOR PRODUCTION**

##### **I. Corporate Documents**

1. All of Your policies and procedures, including updates and revisions, for complaint handling, statistical analysis of complaints, component rejections, trending, failure investigation, quality assurance testing, Document control, and design validation of ICDs and CRT-Ds, with respect to the following device models: Micro Jewel II Model 7223Cx; GEM DR Model 7271; Medtronic Marquis VR Model 7230; Marquis DR Model 7274; Maximo VR Model 7232; Maximo DR Model 7278; InSync Marquis Model 7277; InSync II Marquis Model 7289; and InSync III Marquis Model 7279.

2. Any and all documents relating to customer, patient, and physician complaints, component rejections, and returned Devices or Device components.
3. All reports relating to American, European, or Puerto Rican component suppliers, quality control, or component performance of ICDs and CRT-Ds.
4. All Communications with American, European, or Puerto Rican component suppliers Concerning production, specification of capacitors, and batteries for ICDs and/or CRT-Ds.
5. All standard operating procedures and all revisions for Medtronic Medical Device Reporting from 1996 through the present.
6. Any and all documents depicting the organizational structure and/or hierarchy with regard to communicating within Your company relating to ICD or CRT-D failures, malfunctions, and/or defects from 1996 through the present.
7. All "Alternative Summary Reporting" by Defendant for ICDs and CRT-Ds.
8. All product complaint forms and component or product field reports for implanted and/or explanted ICD and CRT-D devices, including reports in the medical literature regarding ICD and CRT-D device failure or malfunction. Please include with this request all filed medical device reports and subsequent failure investigation files.
9. All of Defendant's reports generated from analysis of explanted ICDs or CRT-Ds and any other documents relating to such analysis.
10. All documents relating to Defendant's policy, including all revisions, for health hazard evaluation from 1996 through the present, including but not limited to, all of Defendant's health hazard evaluations, with all supporting documentation, relating to ICDs and CRT-Ds.
11. All Documents relating to Defendant's policy, including all revisions, for conducting recalls from 1996 through the present.



12. All reports, logs, notes, journals, memoranda, written correspondence or other Documents relating to any ICD and/or CRT-D manufactured or assembled by Defendant which did not pass quality control inspection, including any logs reflecting the final disposition of these ICDs and/or CRT-Ds.

13. All Documents identifying Defendant's policies and procedures for the retention and/or destruction of Documents.

14. All Documents relating to instructions, training procedures or direction of any sort provided by You to persons responsible for handling customer inquiries, physician inquiries, technical inquiries, and/or sales inquiries, concerning or relating to any problems or Defects or recalls of Defendant's ICDs or CRT-Ds.

15. All Documents, including testing protocols and procedures, internal communications, discussions, tests, or analysis relating to any problems, Defects, and/or complaints relating to Defendant's ICDs or CRT-Ds, including all Documents relating to how to fix or remedy any such problems or Defects, and all documents relating to any alterations to or changes in any of the ICDs and CRT-Ds.

16. All Documents relating to when Defendant first learned of any problems, concerns, or risks associated with its ICDs and CRT-Ds, including information relating to Defects leading to battery depletion.

17. All drafts of the PMA/PMA Supplement submissions for each of the ICDs and CRT-Ds.

**II. FDA and/or MHRA Documents**

18. All Documents, including but not limited to reports, relating to the FDA and/or MHRA audits of, reviews of, or comments relating to any aspect of ICD and CRT-D batteries and/or high voltage capacitors, including but not limited to: copies of all reports responsive to the general conditions of approval, annual reports, preclinical testing with

bench testing and animal testing, clinical trial-protocol, investigator agreement, investigator information, any information provided to the FDA for real time review, and post approval studies relating to any of the following PMAs: 980016, 9000061, 010031, 010015, 980050, 930039.

19. All post-approval Communications between Defendant and the FDA and/or MHRA relating to ICDs and CRT-Ds, including, but not limited to, all Communications regarding performance issues, battery design, or battery failure.

20. All Documents, including but limited to Communications, relating to PMA Supplements submitted to the FDA in connection with the following PMAs: 980016, 9000061, 010031, 010015, 980050, 930039.

21. All Communications between Defendant and the FDA and/or the MHRA, including, but not limited to, copies of product testing and failure investigation; manufacturing and quality control actions; recall, removal, product withdrawal, or rework of products with the Defect; and actions that were instituted to quarantine and destroy involved products; adverse event reports relating to non-functional devices; Medical Device Alerts relating to Defendant ICDs and CRT-Ds, including but not limited to the following models of devices: Micro Jewel II Model 7223Cx; GEM DR Model 7271; Medtronic Marquis VR Model 7230; Marquis DR Model 7274; Maximo VR Model 7232; Maximo DR Model 7278; InSync Marquis Model 7277; InSync II Marquis Model 7289; and InSync III Marquis Model 7279.

22. Documents sufficient to Identify every contact between Defendant and the FDA and/or any Foreign Government Regulatory Agency in connection with and/or related to ICD and/or CRT-D medical device approvals and recalls.

23. All Documents sufficient to Identify the conditions of approval for Defendant's PMA Supplements and all Documents that show that Defendant satisfied those conditions and met FDA requirements.

**III. Marketing/Promotions**

24. All Communications between Defendant and physicians relating to the performance of the following models of devices: Micro Jewel II Model 7223Cx; GEM DR Model 7271; Medtronic Marquis VR Model 7230; Marquis DR Model 7274; Maximo VR Model 7232; Maximo DR Model 7278; InSync Marquis Model 7277; InSync II Marquis Model 7289; and InSync III Marquis Model 7279.

25. All Communications with Defendant's sales agents and distributors relating to the recall, removal, product withdrawal of any of Defendant's ICDs and CRT-Ds.

26. All product newsletters, bulletins, or updates generated by Defendant, and intended for sales personnel and/or distribution to the field for ICDs and CRT-Ds, including all updates regarding "premature battery failure."

27. All labeling for ICDs and CRT-Ds from 1996 through the present.

28. All presentations, including PowerPoint, intended for physicians, patients, medical staff, and the United Kingdom MHRA, relating to performance of Defendant's ICDs and CRT-Ds.

29. All of Defendant's brochures intended for distribution to patients and physicians, relating to Defendant's ICDs and CRT-Ds.

30. All physician training manuals, including all drafts and updates, for the following models of devices: Micro Jewel II Model 7223Cx; GEM DR Model 7271; Medtronic Marquis VR Model 7230; Marquis DR Model 7274; Maximo VR Model 7232; Maximo DR Model 7278; InSync Marquis Model 7277; InSync II Marquis Model 7289; and InSync III Marquis Model 7279.

31. All market and sales Communications or information provided to field agents, physicians or hospitals relating to “retrieval,” recall, or substitution of ICD or CRT-D devices manufactured prior to December 2003.

32. All sales information, marketing information, written sales materials, written promotional materials, marketing or sales videotapes, sales launch, films, or other sales or promotional materials or press releases relating to the following models of devices: Micro Jewel II Model 7223Cx; GEM DR Model 7271; Medtronic Marquis VR Model 7230; Marquis DR Model 7274; Maximo VR Model 7232; Maximo DR Model 7278; InSync Marquis Model 7277; InSync II Marquis Model 7289; and InSync III Marquis Model 7279. Please include with this request, any presentations intended for physicians, patients, or medical staff, relating to said devices.

33. All Documents Identifying what action Defendant has taken to warn patients and their physicians of dangers or potential dangers associated with its ICDs and CRT-Ds.

**IV. Third Party Documents**

34. All notes, correspondence, memoranda, logs, or other Documents received by Defendant from any medical care provider, physician, surgeon, electro-physiologist or cardiologist relating to alleged problems or concerns with the design, manufacture, assembly, inspection, failure rate, or potential for failure, battery depletion, sudden battery depletion, battery failure, or quality control of the following models of devices: Micro Jewel II Model 7223Cx; GEM DR Model 7271; Medtronic Marquis VR Model 7230; Marquis DR Model 7274; Maximo VR Model 7232; Maximo DR Model 7278; InSync Marquis Model 7277; InSync II Marquis Model 7289; and InSync III Marquis Model 7279.

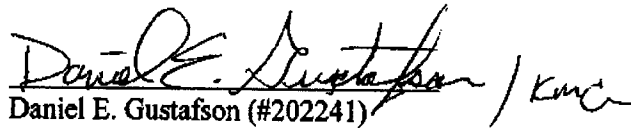
35. Documents sufficient to Identify all companies or third parties retained by Defendant in connection with the design, patents, development, testing, approval, marketing, and/or recall of ICDs and/or CRT-Ds.

36. Documents regarding design, manufacturer and quality assurance of batteries and capacitors of ICDs and/or CRT-Ds.

37. All Documents that describe or relate to finding and/or results of any investigation or review in regard to the manufacture, promotion, marketing sale, distribution, servicing or repair of Defendant's ICDs and CRT-Ds relating to Defects of Defendant's ICDs and CRT-Ds, including but not limited to, all Documents Identifying each and every Defendant ICD or CRT-D sold, including Documents Identifying any product serial number or Identifying marks, Identifying to whom the product was sold, Identifying in whom the product has been placed, including names, addresses or location of implantation of the product.

38. All Documents, literature, memoranda, email and marketing literature regarding product launch for each of the device PMA's and Supplement PMA's.

Dated: February 1, 2006



Daniel E. Gustafson (#202241)  
**Gustafson Gluek PLLC**  
650 Northstar East  
608 Second Avenue South  
Minneapolis, MN 55402  
Tel: (612) 333-8844  
Fax: (612) 339-6622  
Email: [dgustafson@gustafsongluek.com](mailto:dgustafson@gustafsongluek.com)

Charles S. Zimmerman (#102254)  
**Zimmerman Reed P.L.L.P.**  
651 Nicollet Mall, Suite 501  
Minneapolis, MN 55402  
Tel: (612) 341-0400  
Fax: (612) 341-0844  
Email: [csz@zimmreed.com](mailto:csz@zimmreed.com)

***Plaintiffs' Co-Lead Counsel***